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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,821	03/28/2006	Kazuaki Okuno	47259-5001-00 (223490)	9193
55694 7590 01/16/2009 DRINKER BIDDLE & REATH (DC) 1500 K STREET, N.W. SUITE 1100 WASHINGTON, DC 20005-1209				
EXAMINER				
SWOPE, SHERIDAN				
ART UNIT		PAPER NUMBER		
1652				
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01/16/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/573,821

**Applicant(s)**

OKUNO ET AL.

**Examiner**

SHERIDAN SWOPE

**Art Unit**

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/55/08)  
Paper No(s)/Mail Date \_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

### **DETAILED ACTION**

Applicants' representative, Mercedes Meyer, contacted the Examiner on January 14, 2009, to clarify the content of the miscellaneous action mailed January 7, 2009. It was concluded that Applicants' interpretation of the requirement, to elect "one specific OmpT cleavage site listed in Claims 12-30, 34, and 35" in the restriction of May 22, 2008, was to elect a single site (amino acid), rather than a cleavage motif. Therefore, the restriction of May 22, 2008 is withdrawn and herein replaced with the restriction requirement below. The restriction requirement below clarifies that Applicants are required to elect a cleavage motif.

#### ***Election/Restrictions***

Claims 1-35 are pending.

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1-11 and 31-33, drawn to a method for cleaving a polypeptide having an OmpT cleavage site using a wild-type OmpT.

Group II, Claims 12-30, 34, and 35, drawn to a method for cleaving a polypeptide using a variant OmpT.

For each of Inventions I and II above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Inventions I and II and one or more of the following inventions, as indicated.

If Group I is elected, elect one specific OmpT cleavage motif listed in Claims 1-11 and 31-33.

If Group II is elected, elect one specific OmpT variant listed in Claims 12-30, 34, and 35.

If Group II is elected, elect one specific OmpT cleavage motif listed in Claims 12-30, 34, and 35.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: The technical feature linking Groups I and II appears to be that they all relate to methods for cleaving proteins using OmpT protease. However, methods for cleaving proteins using OmpT protease were well known in the art. Moreover, Okuno et al, 2002 (IDS) teach cleavage of the peptide RLELYK<sup>4</sup>RHHG (Table 3), which anticipates Claim 1. Therefore Groups I and II share no special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Furthermore, the methods of Groups I and II do not use the same reagents or produce the same results. Accordingly, Groups I and II are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action lack unity of invention for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Payment of fees for examination of additional inventions may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

These inventions are distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, as shown by their different classification. Furthermore, as explained above, searching more than one invention would be a burden on the Office. Therefore, restriction for examination purposes, as indicated, is proper. If Applicants should traverse the instant restriction based on an argument that the inventions or sub-inventions are not distinct, they should provide evidence as to why the skilled artisan would find any restricted inventions or sub-inventions obvious over their elected invention and sub-invention.

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To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/  
Primary Examiner, Art Unit 1652